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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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09/408,905 09/29/99 WALSH K S1237/7011/E

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EXAMINER

NICKOL, G

ART UNIT

PAPER NUMBER

1642

DATE MAILED:

05/14/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/408,905

Applicant(s)

WALSH, KENNETH

Examiner

Gary B. Nickol Ph.D.

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 February 2001.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) 6-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☒ Claim(s) 5 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 14.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

Response to Amendment

The Amendment filed February 28, 2001 (Paper No. 15) in response to the Office Action of December 01, 2000 is acknowledged and has been entered. Claims 1-38 are pending. Claims 6-38 have been withdrawn from further consideration by the examiner under 37 CFR 1.142(b) as being drawn to non-elected inventions. Claims 1-5 are currently under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Rejections Maintained

Claims 1-4 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Cuevas et al. (Eur.J.Med.Res, Vol. 2, pages 465-468, November, 1997) in view of Datta et al. (Cell, Vol. 91, pages 231-241, October, 1997) for the reasons of record in Paper No. 13, pages 4-5.

Applicant argues (Paper No. 15, page 5) that one of ordinary skill in the art would not have been motivated to substitute the Akt molecule as taught by Datta et al. for the FGF molecule as taught by Cuevas et al. to result in the invention as claimed because the only nexus between the two references is that each relates, in a general sense to an apoptotic process and that the expression of Akt in one cell type, would not lead one of ordinary skill in the art to have a reasonable expectation that Akt would be expressed in a completely different cell type (Paper No. 15, page 6). Applicants further argue (Paper No. 15, page 8) that the mere nexus that FGF is

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an apoptosis inhibitor is 1) insufficient to motivate one skilled in the art to select Akt over other apoptosis inhibitor that were available at the time the invention was made; and 2) is insufficient to provide one skilled in the art with a reasonable expectation of success that the selected Akt would be useful for treating disorders mediated by apoptotic cell death in cardiomyocytes, skeletal myocytes, and or vascular endothelial cells.

These arguments have been considered but are not found persuasive. The Cuevas et al. reference details an "in-vivo" approach to preventing myocardial apoptosis which would have clinical implications in humans by the administration of a growth factor, FGF. The Datta et al. reference details the biological role of Akt and its relationship to cell survival. Furthermore, Datta et al. teach that Akt facilitates *growth factor induced* cell survival in a variety of cell types. Hence, not only is there a plausible nexus between the expected outcome (cell survival), but there is also a link between the two molecules: FGF is a growth factor and Akt is a "general-mediator of growth factor-induced survival". Therefore, the references do suggest to one skilled in the art (with a reasonable expectation of success) that the selected Akt would be useful for treating disorders mediated by apoptotic cell death. It must be remembered that the references are relied upon in combination and are not meant to be considered separately as in a vacuum. It is the combination of all of the cited and relied upon references which made up the state of the art with regard to the claimed invention. Applicant's claimed invention fails to patentably distinguish over the state of the art represented by the cited references taken in combination. In re Young, 403 F.2d 754, 159 USPQ 725 (CCPA 1968); In re Keller 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Furthermore, in response to applicants arguments that Datta et al. does not teach, suggest, or render obvious that Akt would be expressed in the types of cells which play a critical role in myocardial infarction is not persuasive. Applicant argues (Paper No. 15, page 6) that the expression of Akt in one cell type, would not lead one of ordinary skill in the art to have a reasonable expectation that Akt would be expressed in a completely different cell type. First, it was well known in the art, and Datta et al. teaches, that Akt is expressed within more than one cell type (2nd column, 2nd full paragraph). Secondly, the claims do not require such a limitation, only that Akt is administered acutely. Narrow limitations contained in the specification cannot be inferred in the claims where the elements not set forth in the claims are linchpin of patentability. See *In re Philips Industries, Inc. v. State Stove & Mfg. Co.*, 522 F.2d 1137, 186 USPQ 458 (CA6 1975), 237 PTJA A-12. While the claims are to be interpreted in light of the specification, it does not follow that limitations from the specification may be read into claims. On the contrary, claims must be interpreted as broadly as their terms reasonably allow. See *Ex parte Oetiker*, 23 USPQ2d 1641 (BPAI, 1992). Applicant is reminded that the claims define the subject matter of his invention and that the specification cannot be relied upon to read limitations into the claims. Thus, Applicant's arguments have not been found persuasive and the rejection is maintained.

Claim 5 remains objected to for the reasons of record in Paper No. 13, page 5.

All other objections are withdrawn in view of applicant's amendments there to.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

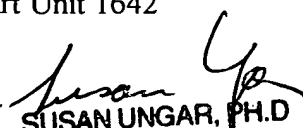
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 703-305-7143. The examiner can normally be reached on M-F, 8:30-5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Gary B. Nickol, Ph.D.
Examiner
Art Unit 1642

GBN
May 8, 2001


SUSAN UNGAR, Ph.D.
PRIMARY EXAMINER